RECORD AND BRIEFS

No. 17-290

Supreme Court, U.S.
FILED
SEP 25 2017
OFFICE OF THE CLERK

In The Supreme Court of the United States

MERCK SHARP & DOHME CORP.,

Petitioner,

v.

DORIS ALBRECHT, ET AL.,

Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Third Circuit

BRIEF OF THE PRODUCT LIABILITY ADVISORY COUNCIL, INC. AND THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AS *AMICI CURIAE* IN SUPPORT OF PETITIONER

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BRIEF OF THE PRODUCT LIABILITY ADVISORY COUNCIL, INC. AND THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AS *AMICI CURIAE* IN SUPPORT OF PETITIONER

INTEREST OF THE *AMICI CURIAE*[1]

The Product Liability Advisory Council, Inc. (PLAC) is a non-profit corporation with 90 corporate members representing a broad cross-section of American industry. Its corporate members include manufacturers and sellers of a variety of products, including automobiles, trucks, aircraft, electronics, cigarettes, tires, chemicals, pharmaceuticals, and medical devices. (A list of PLAC's corporate members is appended to this brief.) PLAC's primary purpose is to file *amicus curiae* briefs in cases that raise issues affecting the development of product liability litigation and have potential impact on PLAC's members.

The Chamber of Commerce of the United States of America (the "Chamber") is the world's largest business federation. It represents 300,000 direct

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[1] Letters of consent from all parties to the filing of this brief have been lodged with the Clerk. Pursuant to S. Ct. Rule 37.2, PLAC and the Chamber state that all parties' counsel received timely notice of the intent to file this brief. Pursuant to S. Ct. Rule 37.6, *amici* state that no counsel for a party wrote this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person or entity, other than the *amici curiae*, their members, or their counsel, has made a monetary contribution to this brief's preparation or submission.

members and indirectly represents the interests of more than three million companies and professional organizations of every size, in every industry sector, from every region of the country. An important function of the Chamber is to represent the interests of its members in matters before Congress, the Executive Branch, and the courts. To that end, the Chamber regularly files *amicus* briefs in cases that raise issues of vital concern to the Nation's business community.

This is such a case. It presents an important question that has produced uncertainty and serious confusion in the lower courts involving the scope of implied conflict preemption in the aftermath of this Court's decision in *Wyeth* v. *Levine*, 555 U.S. 555 (2009). PLAC, the Chamber, and their members have a vital interest in the proper resolution of the question presented.

STATEMENT

1. *The Supremacy Clause and Conflict Preemption.* State and local laws that conflict with federal law are preempted "by direct operation of the Supremacy Clause." *Brown* v. *Hotel & Restaurant Employees & Bartenders Int'l Union Local 54*, 468 U.S. 491, 501 (1984). Although this Court sometimes has separately discussed "impossibility," "obstacle" and ordinary "conflict" preemption, these "terminological" distinctions cannot obscure the fundamental principle that the Supremacy Clause reaches *all* cases where there is an *actual* or *direct* conflict between state and federal requirements. *Geier* v. *Am. Honda Motor Co.*, 529 U.S. 861, 873-74 (2000); see also *Hines* v. *Davidowitz*, 312 U.S. 52, 67

(1941) (discussing wide range of verbal formulations in Court's many cases involving conflict preemption).

The Supremacy Clause serves a vital structural role in our Nation's government by protecting federal law and programs against encroachment and interference by subordinate governments. It also helps to create unified and rational markets for nationally distributed goods and services by ensuring that uniform federal regulation – often the product of expert agency decision-making pursuant to authority delegated by Congress – is not undermined or subverted by state or local law, including state tort law as applied by lay juries. And it ensures that regulated persons, businesses, and other entities are not placed in the impossible position of being compelled to obey directly conflicting legal obligations imposed by federal and state law.

2. *Wyeth* v. *Levine*. In *Wyeth*, this Court addressed the preemptive effect of the Federal Food, Drug and Cosmetic Act (FDCA), 21 U.S.C. § 301 *et seq.*, associated federal regulations relating to drug labeling, and regulatory action by the FDA, on state-law failure-to-warn claims brought against manufacturers of prescription drugs. Federal law, the Court explained, does not preempt such state-law claims if applicable regulations would have allowed the manufacturer unilaterally to alter its previously approved labeling and ultimately FDA would have approved that change, but does preempt if FDA would have rejected that change. 555 U.S. at 568, 570-71 (discussing "Changes Being Effected" (CBE) regulation), 21 C.F.R. § 314.70(c)). When defendant asserted FDA "intended to prohibit it from strengthening the warning" and would have rejected

the warning change proposed by plaintiff, the state courts rejected that contention "as a matter of fact," and this Court affirmed the resulting no-preemption ruling, concluding the record did not contain "clear evidence" supporting defendant's contention; in fact, it contained "*no* evidence . . . that either the FDA or the manufacturer gave more than passing attention to" the risks in question. *Id.* at 572 & n.5 (internal quotation marks omitted; emphasis added).

3. *The Decisions Below.* This case arises out of a multi-district litigation (MDL) involving more than a thousand state-law tort actions, including claims for failure to warn, brought against petitioner Merck Sharpe & Dohme Corp. (Merck), which manufactures an osteoporosis drug called Fosamax. Among other things, plaintiffs claimed Merck should have provided a stronger warning concerning the risk of certain bone fractures.

Following a bellwether trial – and based on a painstaking analysis of "a complete record" (including extensive documentary and other evidence regarding FDA's oversight and regulation of the labeling) – the district court concluded "preemption is warranted because there is clear evidence that the FDA would not have approved a change to the Precautions section of the Fosamax label prior to" plaintiff's injury. Pet. App. 164a, 168a, 169a-174a; see also *id.* at 156a-162a, 168a-174a.

The Third Circuit vacated and remanded. Pet. App. 1a-95a. Parting company with other courts, it held that *Wyeth*'s unelaborated reference to "clear evidence" was meant to impose on the defendant manufacturer a heightened standard of proof akin to the "clear and convincing evidence" test under which

defendant must prove that FDA would have rejected the proposed warning change. Breaking additional new ground, the Third Circuit also ruled that whether FDA would have rejected a warning is a question *for the jury*, even where as here the historical facts are undisputed, and therefore a manufacturer cannot prevail pre-trial, as a matter of law, unless there is a "smoking gun" FDA rejection letter from which a jury could only find the claim preempted. Pet. App. 36a-37a, 54a-55a. Based on those demanding standards, the court of appeals opined that a reasonable jury "could conclude" that FDA would have allowed the labeling change sought by plaintiffs (even though FDA had in fact *rejected* proposed warning language concerning the very risk in question). *Id.* at 67a. The court remanded so juries in individual cases could decide, following a full trial, what FDA would have done.

INTRODUCTION AND SUMMARY OF ARGUMENT

This case raises a recurring and significant question of federal law – and the meaning of the Supremacy Clause – that has vexed and confused the lower courts and is of paramount importance to the pharmaceutical industry. The federal and state courts are deeply confused over the meaning of certain language in *Wyeth* v. *Levine*, 555 U.S. 555 (2009) – specifically, this Court's statement that, while an "impossibility" preemption defense was not available on the particular record developed there, it would have been available if there had been "clear evidence" FDA would have rejected the warning sought by plaintiff. *Id.* at 571. In the decision below, the Third Circuit has adopted a novel gloss on those

two words in *Wyeth* that erects an exceedingly high – and unwarranted – barrier to the use of conflict preemption arguments by pharmaceutical manufacturers. Because only this Court can clarify what it meant in *Wyeth*, further review is needed.

I. The lower courts are confused and sharply divided over the meaning of *Wyeth*'s unelaborated reference to "clear evidence." The Third Circuit candidly acknowledged as much, noting that the meaning of that phrase on its face was "cryptic" and the "lower courts have struggled to make it readily administrable." Pet. App. 28a. The court of appeals also observed that at least two different approaches had been developed in the lower courts, one "more complex" than the other – and then proceeded to reject both in favor of a third reading. *Id.* at 33a-35a; see also *id.* at 35a (concluding that "clear evidence" "does not refer directly to the *type* of facts that" must be demonstrated, "or to the circumstances in which preemption will be appropriate" but rather to "how *difficult* it will be for the manufacturer to convince the factfinder"). In holding that *Wyeth* "intended to announce" a "standard of proof" requiring "clear and convincing" evidence (Pet. App. 35a, 37a), the Third Circuit misread this Court's opinion and parted company with other federal and state decisions.

Indeed, the law in this area is so confused that courts have reached conflicting outcomes on virtually identical regulatory records just as the circuit and district courts did here. Compare, *e.g.*, *Robinson* v. *McNeil Consumer Healthcare*, 615 F.3d 861, 869-70, 873 (7th Cir. 2010) (upholding preemption for Children's Motrin label) with *Reckis* v. *Johnson & Johnson*, 28 N.E.3d 445, 457 (Mass. 2015) (rejecting

preemption). Beyond that, there are numerous tertiary or subsidiary disagreements in the lower courts over precisely what this Court meant by or what qualifies as "clear evidence." Courts and commentators alike have recognized and bemoaned this state of confusion and many have strongly suggested the need for clarification from this Court.

This case presents a valuable opportunity not only to resolve the lower courts' confusion but also to bring greater coherence to federal preemption law. Contrary to the Third Circuit's view, *Wyeth* did not invent a novel, virtually insurmountable burden of proof. Instead, this Court's reference to "clear evidence" merely reflects well-settled precedent establishing that conflict preemption in every form requires demonstration of an *actual*, rather than merely a hypothetical or potential, conflict between federal and state law. See, *e.g.*, *Geier* v. *Am. Honda Motor Co.*, 529 U.S. 861, 884-85 (2000) (conflict preemption "turns on the identification of [an] 'actual conflict[]'" and should not be found "too readily in the absence of *clear evidence* of a *conflict*") (emphasis added); *English* v. *General Electric Co.*, 496 U.S. 72, 90 (1990) (rejecting conflict preemption argument where conflict was "too speculative"). Indeed, *Geier* specifically *rejected* as unworkable and unwieldy a proposal to impose on defendants a "special burden" to establish preemption. In erroneously equating *Wyeth*'s statements with a "clear and convincing" standard of proof, the Third Circuit ignored the origins of the "clear evidence" language in this Court's preemption cases, referring instead to various non-preemption settings that are readily distinguishable. See Pet. 26-27. The Third Circuit also ignored the procedural posture of *Wyeth*, in

which the Court would not have rejected the state courts' factual findings absent "extraordinary" circumstances (*i.e.*, "clear evidence" that those findings were erroneous).

Further review would permit this Court to clarify the nature of the inquiry courts must undertake to determine whether FDA would have approved a labeling change. As petitioner correctly points out, this case is an ideal vehicle for "putting another stake in the ground" that contrasts with *Wyeth* and articulates "an administrable rule of law that *protects* the Supremacy Clause," because petitioner "presented compelling evidence on every front where Wyeth fell short." Pet. 34; *id.* at 28. At the end of the day, only this Court can clarify what it meant by "clear evidence."

II. Review is also warranted because the Third Circuit's flawed approach, if permitted to stand, would create serious negative consequences. The court of appeal's decision deprives litigants of the recognized benefits of preemption as a case-dispositive issue that can be resolved prior to trial; ignores this Court's teachings in both *PLIVA, Inc.* v. *Mensing*, 131 S. Ct. 2567 (2011), and *Mutual Pharmaceutical Co.* v. *Bartlett*, 133 S. Ct. 2466 (2013); creates perverse incentives for manufacturers to burden FDA with constant proposed labeling changes for preemption purposes (an institutional burden this Court declared was important in *Buckman Co.* v. *Plaintiffs' Legal Committee*, 531 U.S. 341 (2001)); and threatens to inhibit drug development by imposing massive additional litigation costs on drug manufacturers in the rising tide of product liability litigation against them. To

avoid these adverse effects, the petition should be granted.

ARGUMENT

I. REVIEW IS NEEDED TO RESOLVE CONFLICTS AND CONFUSION IN THE LOWER COURTS AND CLARIFY *WYETH*'S REFERENCE TO "CLEAR EVIDENCE"

A. The Decision Below Compounds The Confusion In The Lower Courts

As the Third Circuit itself recognized (Pet. App. 33a-36a), there is rampant confusion in the lower courts over the meaning of *Wyeth*'s reference to "clear evidence." The court correctly noted that the meaning of this language, on its face, was "cryptic" and the "lower courts have struggled to make it readily administrable." Pet. App. 28a. The Third Circuit also stated that at least two different approaches had been developed in the lower courts, one "more complex" than the other – and then proceeded to reject both in favor of yet a third reading. *Id.* at 33a-35a; see also *id.* at 35a (concluding that "clear evidence" "does not refer directly to the *type* of facts that" must be demonstrated, "or to the circumstances in which preemption will be appropriate," but rather to "how *difficult* it will be for the manufacturer to convince the factfinder").

The confusion, however, extends well beyond that recognized by the Third Circuit. For example, on the same record involving the same warning for Children's Motrin, the Seventh Circuit and Massachusetts Supreme Judicial Court (SJC) have

reached diametrically opposed conclusions regarding conflict preemption. Compare *Robinson* v. *McNeil Consumer Healthcare*, 615 F.3d 861, 869-70, 873 (2010) (concluding there was "clear evidence" FDA would have rejected proposed warning change) with *Reckis* v. *Johnson & Johnson*, 28 N.E.3d 445, 457-60 (Mass. 2015) (reaching opposite conclusion). Such conflicting outcomes necessarily reflect divergent understandings of what is required by *Wyeth*'s reference to "clear evidence" (just as do the conflicting decisions of the circuit and district courts in this case).

What is more, there are multiple tertiary disagreements – and much confusion – in the lower courts over precisely what qualifies as "clear evidence." Compare, *e.g.*, *Aaron* v. *Wyeth*, 2010 WL 653984, at *6 (W.D. Pa. Feb 19, 2010) (holding manufacturer's proposal to FDA to add warning and FDA's rejection of proposal not "clear evidence" because manufacturer "did not press its position" but "acquiesced" in FDA decision) with *Dobbs* v. *Wyeth Pharmaceuticals*, 797 F. Supp. 2d 1264, 1279 (W.D. Okla. 2011) ("This court disagrees with *Aaron*'s interpretation of the proof standard announced in [*Wyeth*]."). Some courts, in upholding preemption, have relied on FDA's rejection of warnings proposed by *citizen petitions* rather than by the manufacturer under the CBE regulation, whereas others have insisted on the latter. Compare, *e.g.*, *Cerveny* v. *Aventis, Inc.*, 855 F.3d 1091, 1099, 1102 (10th Cir. 2017) (finding "clear evidence" where FDA rejected warning proposed by citizen petition and rejecting argument FDA "accord[s] greater deference to changes proposed by manufacturers than [by]. . .citizen[s]") and *Dobbs*, 797 F. Supp. at 1274

(finding clear evidence based on FDA rejection of citizen petition) with *Reckis*, 28 N.E.3d at 457-60 (concluding FDA's rejection of warnings proposed by citizen petition did not show that agency would have rejected same warning if *manufacturer* had proposed it) and *Baumgardner* v. *Wyeth Pharmaceuticals*, 2010 WL 3431671, at *1 (E.D. Pa. Aug. 31, 2010) (same). See also Thomas Ayala & Elizabeth Graham, *Overcome the Clear Evidence Defense*, 52 Trial 32, 34 & nn. 13-16 (July 2016) (acknowledging this split of authority and discussing additional cases).

These tertiary disagreements exist among those courts that have assumed, contrary to the Third Circuit's holding, that "clear evidence" refers either to "the *type* of facts that" must be demonstrated "or to the circumstances in which preemption will be appropriate," not to "how *difficult* it will be for the manufacturer to convince the factfinder." Pet. App. 35a. The Third Circuit's decision to adopt a "clear and convincing" standard of proof only compounds this confusion.[2] Not surprisingly, many commentators have also recognized the widespread confusion and conflicts in the lower courts. See, *e.g.*,

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[2] The misunderstanding of how the conflict preemption inquiry should be conducted is also reflected in the suggestion of various lower courts that preemption cannot be established unless a manufacturer *actually proposes* the allegedly missing warning, the FDA *actually rejects the manufacturer's proposal*, or both. Requiring such proof denies preemption in precisely those cases involving the most scientifically unfounded warnings, which *no* manufacturer would ever propose (and FDA *unquestionably* would reject). That cannot possibly be the law, nor can it be what this Court meant in *Wyeth*.

Ayala & Graham, *supra*, 52 Trial at 34 & nn. 13-16; Michael Gallagher, *Clear Evidence of Impossibility Preemption After Wyeth v. Levine*, 51 GONZ. L. REV. 439, 440-42 (2015-2016) ("neither courts nor litigants nor commentators know exactly what clear evidence means" and "[c]ourts have issued divergent opinions").

The lower courts have repeatedly noted the absence of and/or need for further guidance from this Court concerning what qualifies as "clear evidence" in this important and recurring setting. See, *e.g.*, *Mason* v. *Smithkline Beecham Corp.*, 596 F.3d 387, 391 (7th Cir. 2010) (because *Wyeth* "did not clarify what constitutes 'clear evidence[,]' . . . the only thing we know for sure" is that the evidence in that case "did not meet" that "standard"); *Dobbs*, 797 F. Supp. 2d at 1270 (noting that "'lower courts are left to determine what satisfies this 'clear evidence' standard'") (quoting *Schilf* v. *Eli Lilly & Co.*, 2010 WL 3909909, at *4 (D.S.D. Sept. 30, 2010)). It is time to heed this call.

B. The Third Circuit Misunderstood *Wyeth*'s Reference To "Clear Evidence"

In the absence of clearer guidance from this Court, the Third Circuit – along with some other courts – have concluded that this Court's reference to "clear evidence" was intended to require more than a mere preponderance of the evidence. The Third Circuit expressly adopted the "clear and convincing" standard of proof, whereas other courts have used different formulations that may or may not be even more demanding. Pet. App. 35a, 37a. See, *e.g.*, *Mason*, 596 F.3d at 391 (describing "clear evidence"

as an "exacting" and "stringent" standard); *Forst* v. *Smithkline Beecham Corp.*, 639 F. Supp. 2d 948, 953 (E.D. Wis. 2009) (under *Wyeth* "a defendant drug manufacturer faces an exacting burden"). But in concluding that "clear evidence" was really "clear *and convincing*" evidence, the Third Circuit relied largely on various non-preemption decisions of this Court that, as petitioner demonstrates, are all readily distinguishable. See Pet. 26-27; Pet. App. 36a-37.

Tellingly, however, the Third Circuit failed to take account of this Court's *conflict preemption* decisions that have articulated the need for "clear evidence" in that setting. Had the Third Circuit done so, it would have recognized that, far from announcing a novel and "exacting" new standard of proof, *Wyeth*'s reference to "clear evidence" merely reflects and expresses well-settled and longstanding principles involving conflict preemption.

Federal preemption is usually raised as an affirmative defense. And in civil actions, the ordinary or default burden of persuasion is proof by a preponderance of the evidence.[3] Thus, a defendant ordinarily must prove any facts necessary for a preemption defense by a preponderance of the

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[3] Although preemption is a *legal* defense, sometimes (as in this setting) the defense can hinge on case-specific regulatory facts and circumstances. In every conflict preemption case, however, a court (1) ascertains the meaning of state law; (2) determines the meaning of federal law; and (3) makes a judgment whether the former conflicts with, or serves as an obstacle to, the latter. *Perez* v. *Campbell*, 402 U.S. 637, 644 (1971).

evidence.[4] In a long line of cases, this Court has made clear that ordinarily the proponent of a conflict preemption defense must demonstrate an *actual* conflict between state and federal law – potential or hypothetical conflicts are not enough. The preemptive conflict, in other words, must be "clear." See, *e.g.*, *Geier* v. *Am. Honda Motor Co.*, 529 U.S. at 861, 884 (2000) (conflict preemption "turns on the identification of 'actual conflict[]'"); *English* v. *General Electric Co.*, 496 U.S. 72, 90 (1990) (rejecting conflict preemption argument where claimed conflict was "too speculative"); *Rice* v. *Norman Williams Co.*, 458 U.S. 654, 664 (1982) (Court's decisions "enjoin seeking out conflicts between state and federal regulation where none *clearly* exists") (emphasis added; quotation marks omitted). "Clear evidence" in this setting thus means what it always has meant:

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[4] Courts and commentators have suggested that, in cases such as this, the burden of proof ought to be placed on plaintiff in whole or at least in part. See David Geiger & Andrew London, *Wyeth's "Clear Evidence" Language: Clearly Misunderstood*, Law360 (Jan. 12, 2016) (arguing that, in light of the federal regulatory scheme, plaintiff should bear the burden to prove what constitutes an exception to the preemption that would otherwise exist once defendant proved it was using FDA-approved labeling); *Utts* v. *Bristol-Myers Squibb Co.*, 2017 WL 1906875, at *9, *19 (S.D.N.Y. May 18, 2007) (only after plaintiff "prove[s] the existence of newly acquired information" allowing a manufacturer to submit a CBE does burden shift to manufacturer to show that FDA would have rejected labeling change). And this Court has made clear that preemption is not always "in the nature of an affirmative defense." *Int'l Longshoremen's Ass'n* v. *Davis*, 476 U.S. 380, 381-82, 387-89 (1986) (involving so-called "*Garmon*" preemption under the National Labor Relations Act). Further review would allow the Court to clarify how the burden of proof operates in cases such as this.

the demonstration of an *actual*, as opposed to merely a *potential*, conflict.

This reading is amply confirmed by *Geier*, which also used the "clear evidence" formulation in evaluating proof of conflict preemption. Specifically, this Court in *Geier* reasoned that conflict preemption "turns on the identification of 'actual conflict[]'" and then explained that "a court should not find pre-emption too readily in the absence of *clear evidence* of a *conflict*." 529 U.S. at 884-85 (emphasis added).

In referring to "clear evidence," the Court in *Geier* cited a portion of its previous decision in *English*. The relevant portion of *English* addressed whether administrative anti-retaliation provisions for employees in the nuclear power industry, established by a federal statute, preempted emotional distress tort claims under state law. Rejecting the argument that Congress's inclusion of "expeditious time-frames" in the federal administrative remedy preempted state claims with longer deadlines, the Court expressed skepticism that without preemption "employees will forgo their [federal administrative] options and rely solely on state remedies for retaliation." *English*, 496 U.S. at 89-90. "Such a prospect," the Court explained,

> is simply *too speculative* a basis on which to rest a finding of pre-emption. The Court has observed repeatedly that pre-emption is ordinarily not to be implied absent an 'actual conflict.' See, *e.g.*, *Savage* v. *Jones*, 225 U.S. 501, 533 (1912). The 'teaching of this Court's decisions . . . enjoin[s] seeking out conflicts between state and federal regulation where none

> *clearly* exists.' *Huron Portland Cement Co.* v. *Detroit*, 362 U.S. 440, 446 (1960).

Id. at 90 (emphasis added). The references to "clear evidence" in *Geier* and "clear" conflicts in *English* are thus nothing more than a restatement of the basic principle that, for the Supremacy Clause to come into play, there must be an "actual," and not merely a potential, conflict between federal and state requirements.

Nor is this all. If the Court in *Wyeth* had meant more than the "clear" evidence required in *Geier* and *English* – if it had meant to create a special new ("clear and convincing" or "exacting") standard of proof unique to prescription drug labeling cases – then it surely would have said so. The Court, like Congress, "does not . . . hide elephants in mouseholes." *Whitman* v. *Am. Trucking Ass'ns., Inc.*, 531 U.S. 457, 468 (2001).

The Third Circuit's reading of *Wyeth* is especially implausible for at least two additional reasons. First, in *Geier* the Court expressly *rejected* an argument that a defendant must shoulder a "special burden" of proof in certain subcategories of implied preemption cases. 529 U.S. at 870-74. Such a "special burden," the Court explained in words that are equally applicable to the Third Circuit's holding, "find[s]" no "basis . . . in this Court's precedents" and would "promise practical difficulty by further complicating well-established pre-emption principles that already are difficult to apply." *Id.* at 872-73. In light of that holding, *Geier*'s reference to "clear evidence" obviously did not alter the ordinary burden of establishing a preemption defense. Nor is it plausible to conclude that the Court in *Wyeth*

intended to adopt the very kind of "special burden" rejected in *Geier* (without even mentioning this aspect of that decision).

Second, the Third Circuit's suggestion that *Wyeth* intended to create a "clear and convincing" proof standard (even though that issue was neither raised nor briefed there) overlooks the procedural posture of that case. In *Wyeth*, the Court was evaluating the drug manufacturer's argument in light of factual findings made by two lower state courts, including that (1) certain warnings rejected by FDA were not materially different from the allegedly defective warning that actually accompanied the product, and (2) FDA did not intend to prohibit the manufacturer from strengthening the warning. See 555 U.S. at 572 & n.5. This Court's statement that there must be "clear evidence" was no doubt informed by this procedural posture and what would be necessary to overcome the state courts' factual findings. See *324 Liquor Corp.* v. *Duffy*, 479 U.S. 335, 351 (1987) (this Court "customarily accept[s] the factual findings of state courts in the absence of exceptional circumstances"); see also Geiger & London, *supra*, Law360 ("'clear evidence' language was necessitated by the fact that the preemption issue turned on factual findings made by the Vermont courts, which the Supreme Court could not ordinarily reverse absent exceptional circumstances").

Further review would allow this Court to clarify that *Wyeth* did not intend to adopt a "clear and convincing" (or for that matter a "stringent" or "exacting") standard of proof unique to pharmaceutical cases. It would also permit the

Court to resolve some of the tertiary disagreements in the lower courts described above, by making clear that *any* type of proof showing by a preponderance of the evidence that FDA would have rejected a warning (including, for example, a rejected citizen petition) can qualify as "clear evidence."

C. Only This Court Can Clarify What It Meant in *Wyeth*

At bottom, the serious confusion in the lower courts stems from this Court's unelaborated reference in *Wyeth* to "clear evidence." For that reason, further litigation in the lower courts is unlikely to lead to greater clarity. Instead, as the experience since *Wyeth* confirms, it will only produce greater confusion and uncertainty. The Third Circuit's decision is illustrative: it only adds new and different approaches and deepens the confusion.

As this Court has recognized, the law of federal preemption is complicated and "difficult to apply." *Geier*, 529 U.S. at 873. Some of this Court's preemption decisions have featured multiple opinions that combine to form the Court's majority. See, *e.g.*, *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470 (1996); *Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504 (1992). When ambiguities in those decisions have led to conflicting interpretations and confusion in the lower courts, this Court has not hesitated to step in to restore uniformity. See, *e.g.*, *Freightliner* v. *Myrick*, 514 U.S. 280, 288-89 (1995) (clarifying statement in *Cipollone* that had spawned lower court confusion regarding availability of implied preemption under statutes with express preemption clauses); *Geier*, 529 U.S. at 872-73 (discussing same).

The Court should do so here too. Ultimately, only this Court can offer definitive guidance on what it meant in *Wyeth*.

II. THE THIRD CIRCUIT'S DECISION IGNORES THIS COURT'S PRE-EMPTION TEACHINGS AND WILL CAUSE HARMFUL CONSEQUENCES

Not only did the Third Circuit impose on pharmaceutical manufacturers a demanding and unwarranted "clear and convincing evidence" burden of proof, but it also held that whether FDA would have rejected a proposed warning is a question for the jury, even when the historical facts are undisputed. Pet. App. 36a-37a, 46a-47a n.122, 54a-55a. As a consequence, conflict preemption will be relegated to a jury in situations even where, as here, the record clearly shows it is more likely than not that FDA would have rejected the proposed warning. See Pet. i, 28; Pet. App. 59a-60a. As well, under the decision below a manufacturer cannot prevail on the preemption defense pre-trial, as a matter of law, unless there is a "smoking gun" rejection letter from FDA that would leave a jury no choice but to find the state-law claim preempted. The Third Circuit's highly restrictive two-part gloss on *Wyeth* ignores this Court's teachings and, if permitted to stand, will have multiple adverse effects. For those reasons as well, review is warranted.

a. *Preemption's Value as a Threshold Legal Issue.* In most settings, courts treat preemption as a defense that is susceptible to being resolved on purely legal grounds at the threshold of or early in litigation (typically on a motion to dismiss or for

summary judgment). Cf. note 4, *supra*. Much of the practical benefit of the doctrine stems from its capacity to ensure that litigants are not forced to endure lengthy and costly discovery proceedings, and even trial, defending against state-law claims that violate the Supremacy Clause.

This Court has recognized the need to preserve this salutary function of preemption. For example, where preemption hinges on the allegations made in a complaint, the Court has repeatedly stated that plaintiffs may not avoid preemption through artful pleading. See, *e.g.*, *Aetna Health Inc.* v. *Davila*, 542 U.S. 200, 214 (2004) ("[D]istinguishing between pre-empted and non-pre-empted claims based on the particular label affixed to them would 'elevate form over substance and allow parties to evade' the pre-emptive scope of ERISA simply 'by relabeling their contract claims as claims for tortious breach of contract.'") (quoting *Allis-Chalmers Corp.* v. *Lueck*, 471 U.S. 202, 211 (1985)); *Chicago & N.W. Transp. Co.* v. *Kalo Brick & Tile Co.*, 450 U.S. 311, 324 (1981) ("[C]ompliance with the intent of Congress cannot be avoided by mere artful pleading."). But the Third Circuit's decision allows a litigant to avoid summary judgment merely by claiming that FDA's decision rejecting a warning concerning the risk in question might have been different if the warning had been worded only slightly differently. It is no more difficult to conjure up hypothetical alternative wordings for a warning than it is to use artful pleading in a complaint. See Pet. 23.

b. *This Court's Teachings in* PLIVA *and* Bartlett. This Court has not hesitated to *reject* speculative scenarios advanced by plaintiffs as

grounds for denying preemption. Illustrative are *PLIVA, Inc.* v. *Mensing*, 131 S. Ct. 2567 (2011), and *Mutual Pharmaceutical Co.* v. *Bartlett*, 133 S. Ct. 2466 (2013). Thus, in *PLIVA*, the Court rejected the argument that a generic drug manufacturer (which is obligated by federal law to use the same labeling as the brand-name drug) could have asked the FDA to change both its own and the brand-name label, and such a request might ultimately have resulted in FDA permission to change the generic-drug labeling. 131 S. Ct. at 2578-79. Because the manufacturer had not even *tried* to persuade the FDA to do so, the plaintiffs contended, the manufacturer could not establish conflict preemption. This Court emphatically rejected that argument, explaining that "[i]f these conjectures suffice to prevent federal and state law from conflicting for Supremacy Clause purposes," then conflict preemption would be rendered "largely meaningless." *Ibid.*

For exactly the same reason, this Court in *Bartlett* rejected plaintiff's contention that a drug manufacturer could avoid the direct conflict between federal and state law merely by electing to stop selling the medication altogether. See *Bartlett*, 133 S. Ct. at 2477 (accepting that argument would render impossibility preemption "meaningless"). The Third Circuit did not explain how its decision to relegate to *the jury* an equally speculative hypothetical scenario (notwithstanding all the record evidence here that FDA would have rejected the proposed warning) can be squared with *PLIVA* or *Bartlett*.

c. *Burdens on the FDA.* The Third Circuit's flawed approach would likely also burden the federal

regulatory process governing drug labeling. The decision below creates powerful incentives for drug manufacturers to constantly propose labeling changes to the FDA to ensure that plaintiffs cannot defeat preemption by invoking hypothetical alternative language.

In *Buckman Co.* v. *Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), which held that fraud-on-the-FDA claims are impliedly preempted, this Court emphasized the need to avoid such unwarranted burdens on FDA's regulatory processes. Specifically, the Court explained the negative impact such claims would have on the agency's approval of certain categories of medical devices:

> [F]raud-on-the-FDA claims would also cause applicants to fear that their disclosures to the FDA, although deemed appropriate by the Administration, will later be judged insufficient in state court. Applicants would then have an incentive to submit a deluge of information that the Administration neither wants nor needs, resulting in additional burdens on the FDA's evaluation of an application. As a result, the comparatively speedy [approval] process could encounter delays. . . .

531 U.S. at 351. In much the same way, the Third Circuit's flawed approach to conflict preemption will multiply the burdens on FDA's review process with respect to drug labeling.

d. *Effects on Drug Development and the Rising Tide of Pharmaceutical Litigation.* Developing drugs is very expensive. See, *e.g.*, J.A. DiMasi et al., *Innovation in the Pharmaceutical Industry: New*

Estimates of R&D Costs, at 5 (Nov. 18, 2014) (estimated average industry cost of new prescription drug approval, inclusive of failures and capital costs, is $2.59 billion) (http://csdd.tufts.edu/files/uploads/Tufts_CSDD_briefing_on_RD_cost_study_-_Nov_18,_2014..pdf). A manufacturer will not invest the vast sums necessary to develop a drug unless it believes it can recoup its investment. Allowing failure-to-warn claims to proceed under the varying tort laws of the fifty states despite a preponderance of the evidence that FDA would not have approved the proposed warnings would impose significant and unpredictable defense and liability costs on manufacturers, and thereby reduce their willingness to invest in developing new drugs. As the Tenth Circuit recently observed in the context of medical devices, "[r]equiring manufacturers to comply with fifty states' warning requirements ... on top of existing federal ... requirements, might introduce sufficient uncertainty and cost that manufacturers would delay or abandon at least some number of life-saving innovations." *Caplinger* v. *Medtronic, Inc.*, 784 F.3d 1335, 1346 (10th Cir. 2015) (Gorsuch, J.). The Third Circuit's decision will increase the costs and uncertainty of litigation faced by manufacturers by requiring more trials and placing the preemption issue in the hands of lay juries.

This is no idle concern. The extent of federal litigation against pharmaceutical companies, already immense, is rapidly expanding. The MDL proceedings in this case alone involve more than 1000 lawsuits. Moreover, in 2016 there were 21,517 product liability lawsuits filed against pharmaceutical companies in the federal courts, up from 6,791 just five years ago and 2,700 in 2001. See

Admin. Office of the U.S. Courts, Table C-2A: *U.S. District Courts--Civil Cases Commenced, by Nature of Suit, During the 12-Month Periods Ending September 30, 2012 Through 2016,* http://www.uscourts.gov/sites/default/files/data_tables/jb_c2a_0930.2016.pdf; Lisa Girion, *State Vioxx Trial Is Set as Drug Suits Boom,* L.A. Times, June 27, 2006, at C1. Today, out of seventy-three pending product liability MDL proceedings, twenty-eight, or *over 38%*, involve pharmaceuticals. See U.S. Judicial Panel on Multidistrict Litig., MDL Statistics Report – Distribution of Pending MDL Dockets by District (Aug. 15, 2017), http://www.jpml.uscourts.gov/sites/jpml/files/Pending_MDL_Dockets_By_District-August-15-2017.pdf. By comparison, between 1960 and 1999, there were only five MDL product liability actions involving FDA-approved medicines. See Deborah Hensler, *Has the Fat Lady Sung? The Future of Mass Toxic Torts,* 26 REV. LITIG. 883, 897-902 tbl. 1.1 (2007).

CONCLUSION

For the foregoing reasons, and those set forth in the petition for a writ of certiorari, the petition should be granted.

Respectfully submitted.

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SEPTEMBER 2017

APPENDIX

PRODUCT LIABILITY
ADVISORY COUNCIL, INC.
LIST OF CORPORATE MEMBERS

3M
Altec, Inc.
Altria Client Services Inc.
Astec Industries
Bayer Corporation
BIC Corporation
Biro Manufacturing Company, Inc.
BMW of North America, LLC
The Boeing Company
Bombadier Recreational Products, Inc.
Boston Scientific Corporation
Bridgestone Americas, Inc.
Bristol-Myers Squibb Corporation
C.R. Bard, Inc.
Caterpillar Inc.
CC Industries, Inc.
Celgene Corporation
Chevron Corporation
Cirrus Design Corporation
Continental Tire the Americas LLC
Cooper Tire & Rubber Company
Cordis Corporation
Crane Co.
Crown Equipment Corporation
Daimler Trucks North America LLC
Deere & Company
Delphi Automotive Systems
The Dow Chemical Company
E.I. duPont de Nemours and Company

Emerson Electric Co.
Exxon Mobil Corporation
FCA US LLC
Ford Motor Company
Fresenius Kabi USA, LLC
General Motors LLC
Georgia-Pacific LLC
GlaxoSmithKline
The Goodyear Tire & Rubber Company
Great Dane Limited Partnership
Hankook Tire America Corp.
Harley-Davidson Motor Company
The Home Depot
Honda North America, Inc.
Hyundai Motor America
Illinois Tool Works Inc.
Intuitive Surgical, Inc.
Isuzu North America Corporation
Jaguar Land Rover North America, LLC
Johnson & Johnson
Kawasaki Motors Corp., U.S.A.
Kia Motors America, Inc.
Kolcraft Enterprises, Inc.
Kubota Tractor Corporation
Lincoln Electric Company
Magna International Inc.
Mazak Corporation
Mazda Motor of America, Inc.
Medtronic, Inc.
Merck & Co., Inc.
Meritor WABCO
Michelin North America, Inc.
Microsoft Corporation
Mitsubishi Motors North America, Inc.
Mueller Water Products

Newell Brands Inc.
Novartis Pharmaceuticals Corporation
Novo Nordisk, Inc.
Pella Corporation
Pfizer Inc.
Polaris Industries, Inc.
Porsche Cars North America, Inc.
RJ Reynolds Tobacco Company
Robert Bosch LLC
The Sherwin-Williams Company
Sony Electronics Inc.
Stryker Corporation
Subaru of America, Inc.
TAMCO Building Products, Inc.
Teleflex Incorporated
Toyota Motor Sales, USA, Inc.
Trinity Industries, Inc.
The Viking Corporation
Volkswagen Group of America, Inc.
Volvo Cars of North America, Inc.
Wal-Mart Stores, Inc.
Western Digital Corporation
Whirlpool Corporation
Yamaha Motor Corporation, U.S.A.
Yokohama Tire Corporation
ZF TRW